UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MATTHEW R. KASER, YALDA AZIMZAI and HENRY YUE

Appeal No. 2006-0186
Application No. 09/838,044

ORDER UNDER 37 CFR § 41.50(d)

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),[1] we require Appellants to address the following matters:

First, section (2) of the Appeal Brief, dated January 21, 2004, states that

> Appellants, their legal representatives and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

[1] "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

Nevertheless, as appellants are aware, there are a large number of applications, as evidenced by the discussion below, which have issues in common with the instant appeal. Explanation or clarification of this apparent inconsistency is required.

Second, we invite attention to Application No. 09/209,859 where, according to Patent and Trademark Office (PTO) records, appellants filed a Notice of Appeal from the examiner's final rejection on April 27, 2001.[2] After a briefing stage and oral hearing on February 21, 2003, another panel of the Board handed down its decision in the '859 application, affirming the examiner's final rejection of claim 1 and 11 (Appeal No. 2002-0774, BPAI 2003).

We think it clear that Appeal No. 2002-0774, in Application No. 09/209,859, bears close relationship to the instant appeal. In Appeal No. 2002-0774, the claims are drawn to a substantially purified polypeptide, viz., a transmembrane protein designated ONMO having the amino acid sequence shown in SEQ ID NO: 1; as well as naturally occurring variants and biologically active fragments thereof, and pharmaceutical compositions comprising any of those polypeptides in conjunction with a pharmaceutical carrier. The sole issue was whether appellants' claims were supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.

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[2] The named inventors on the instant application are Matthew R. Kaser, Yalda Azimzai and Henry Yue.. In Application No. 09/209,859, the inventors are Jennifer L. Hillman, Surya K. Goli, Olga Bandman and Karl J. Guegler. The applications are commonly assigned.

In what the previous panel referred to as "a second line of argument" or "a second line of reasoning," appellants argued that their claimed polypeptides have utility because all expressed human genes and polypeptides have utility as research tools (Application No. 09/209,859, Paper No. 28, page 9, lines 3 through 5; and paragraph bridging pages 10 and 11). Appellants reasoned that the technique of expression profiling, in which the expression of numerous genes is compared in two or more samples, is used in research relating to toxicology testing, drug development and disease diagnosis; that "[g]enes or gene fragments known to be expressed, such as the invention at issue, are tools essential to any technology that uses expression profiling;" that "[t]he more genes that are available for use in toxicology testing, the more powerful the technique;" and that "there is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening. This is true for both polynucleotides and polypeptides encoded by them." Id., paragraph bridging pages 10 and 11.

Additionally, appellants argued before the previous merits panel that "[as] used in toxicology testing, drug discovery, and disease diagnosis, the claimed invention has a beneficial use in research other than studying the claimed invention . . . It is a tool, rather than an object, of research." According to appellants, that distinguished their case from reported cases like Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), and In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967), where "the only known use for the claimed invention

[was] to be an object of further study." Id., page 11, first full paragraph. Appellants also argued that § 101 is satisfied by utilities that apply equally to all expressed human genes and proteins; the utility need not be "particular" to the claimed invention. "Practical real-world uses are not limited to uses that are unique to an invention." According to appellants, "all isolated and purified naturally occurring polynucleotide and polypeptide sequences which are expressible . . . can be and are used in a real-world context as tools for toxicological testing, e.g., for drug discovery purposes." Id. page 12, second full paragraph.

The previous merits panel reviewed governing principles of law; addressed and rejected appellants' "second line of argument;" and concluded that "[a]ppellants' disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id. page 31, lines 2-4. Accordingly, the examiner's decision, rejecting claims 1 and 11 under 35 U.S.C. § 101 in Application No. 09/209,859, was affirmed.

Similar to the claims in Application No. 09/209,859, the claims in this appeal are drawn to a substantially purified protein expressed in response to polycyclic aromatic hydrocarbon exposure, and compositions thereof. All of the appealed claims stand rejected under 35 U.S.C. § 101 "because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well-established utility." Examiner's Answer, page 3.

The Appeal brief in this appeal includes essentially the same "second line of argument" addressed by the previous merits panel in Appeal No. 2002-0774.[3] For example, appellants argue that "[t]he use of proteins expressed by humans as tools for toxicology testing, drug discovery, and the diagnosis of disease is now 'well-established,'" Appeal Brief, page 11; that "[t]he more genes – and accordingly, the polypeptides they encode - that are available for use in toxicology testing, the more powerful the technique. . . .Thus, there is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening," id. at 12; that "the claimed invention is a tool, rather than an object, of research," id. at 26; that "[o]ver the past several years, a vibrant market has developed for databases containing all expressed genes (along with the polypeptide translations of those genes). (Note that the value in these databases is enhanced by their completeness, but each sequence in them is independently valuable)," id. at 22; and that "broad classes of inventions can satisfy the utility requirement so long as a person of ordinary skill in the art would understand how to achieve a practical benefit from knowledge of the class," id. at 30.

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[3] We note that the evidence of record in this case differs from that of 2002-0774, in that the examiner has entered and responded to Appellants' declaratory evidence submitted with the Appeal Brief. The panel in 2002-0774, however, "assum[ed] arguendo that the use of polypeptides to monitor gene expression in research related to toxicology testing, drug development, and disease diagnosis was well-established as [of] the application's filing date." Application No. 09/209,859, Paper No. 28, page 14. The panel then went on to explain in detail why Appellants' "expression profiling" argument was unconvincing, even assuming it was supported by evidence. See id., pages 14-31. Since the Furness, Bedilion and Iyer declarations, as well as the references cited, appear to be directed to providing evidence in support of the same "expression profiling" argument, the panel's analysis in 2002-0774 appears to be equally applicable to this case.

On these facts, we require that appellants explain why we should address anew the "second line of argument" in this case. Respecting the issue raised by the "second line of argument," that same issue having been raised previously in Appeal No. 2002-0774, why would the previous panel's treatment of the issue not be dispositive here? In particular, why should the facts and arguments set forth in appellants' Appeal Brief lead to a different conclusion than that reached by another panel in Appeal No. 2002-0774 rejecting appellants' "second line of argument?" We note in passing that, according to PTO records, the appellants in Appeal No. 2002-0774 did not request rehearing under 37 CFR § 1.197(b) (now 37 CFR § 41.52), nor did they appeal the Board's decision.

Third, we invite appellants' attention to In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005), where the Court of Appeals for the Federal Circuit addressed the utility requirement. The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case was either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fishers seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, as in Fisher, the generic uses – toxicology testing, drug discovery and disease diagnosis using gene expression monitoring applications such as the use of the polynucleotide in a microarray – asserted by appellants do not appear to be substantial nor specific utilities. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 1373, 76 USPQ2d 1231 (emphasis in original). Those utilities could be asserted for any cDNA transcribed from any gene in the human genome.

Thus, we require appellants to include a discussion of the relevance of Fisher to the appealed claims.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2002-0774. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response. This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

Toni R. Scheiner)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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Lora M. Green) INTERFERENCES
Administrative Patent Judge)

INCYTE CORPORATION
EXPERIMENTAL STATION
ROUTE 141 & HENRY CLAY ROAD
BLDG. E336
WILMINGTON DE 19880